

WHAT IS CLAIMED IS:

1. An isolated HP30 or HP56 polypeptide of *Helicobacter* spp, wherein the HP30 has a molecular weight of 30 kDa and the HP56 kDa has a molecular weight of 56 kDa as
5 determined in SDS polyacrylamide gel electrophoresis.
2. The HP30 or HP56 polypeptide of claim 1, wherein the *Helicobacter* spp. is selected from the group consisting of *Helicobacter pylori* and *Helicobacter felis*.
- 10 3. The HP30 or HP56 polypeptide of claim 2, wherein the *Helicobacter* spp is *Helicobacter pylori*.
4. The HP56 or HP30 polypeptide of claim 1, comprising sequence SEQ ID NO: 2 or 4, a fragment thereof, a sequence encoded by a nucleic acid molecule comprising the
15 sequence SEQ ID NO: 1 or 3, a fragment thereof, or a sequence encoded by a nucleic acid molecule which hybridizes to a nucleic acid molecule comprising the sequence of SEQ ID NO: 1 or 3 under high stringency conditions comprising (a) prehybridization of filters with DNA at 50°C in buffer comprised of 6 x SSC, 50 mM Tris-HCl (pH 7.5), 1mM EDTA, 0.02% PVP, 0.02% Ficoll, 0.02% BSA and 500 mg/ml denatured salmon sperm DNA; (b)
20 hybridization at 65°C in prehybridization mixture containing 100 mg/ml denatured salmon sperm DNA and (c) washing of filters at 37°C in solution containing 2x SSC, 0.01% PVP, 0.01% Ficoll 0.01% BSA, wherein said fragment is at least 6 amino acids in length.
5. The HP56 or HP30 polypeptide of claim 1 or an at least 6 amino peptide fragment
25 thereof, which specifically binds an antibody that specifically binds to a protein having the sequence selected from the group consisting of SEQ ID NOs: 2 and 4.
6. A peptide fragment of the HP30 or HP56 polypeptide of claim 1, wherein said peptide fragment is at least 6 amino acids in length.
30
7. The peptide fragment of claim 6 wherein said fragment comprises the sequence of SEQ ID NO: 5-20.
8. An isolated fusion polypeptide comprising at least two peptides, each of said
35 peptides selected from the group of peptides having an amino acid sequence selected from sequences consisting of the SEQ ID NOS:5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19

and 20 with the proviso that the peptides are arranged in a configuration that is different from naturally occurring configuration.

9. The isolated fusion polypeptide of claim 8 wherein the fusion polypeptide comprises
5 SEQ ID NO: 5, 6, 7, 8, 9, 10 and 11 with the proviso that the peptides of said fusion polypeptide are arranged in a configuration that is different from naturally occurring configuration.

10. The isolated fusion polypeptide of claim 8 wherein the fusion polypeptide comprises
10 SEQ ID NO: 16, 17, 18, 19, and 20, with the proviso that the peptides of said fusion polypeptide are arranged in a configuration that is different from naturally occurring configuration.

11. An antibody or an antigen-binding fragment thereof that specifically binds the HP56
15 or HP30 polypeptide of claim 1.

12. An antibody or an antigen-binding fragment thereof that specifically binds the peptide fragment of claim 6.

20 13. An antibody or an antigen-binding fragment thereof that specifically binds a peptide fragment having an amino acid sequence selected from the group consisting of SEQ ID NO:5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, and 20.

14. The antibody of claim 11, 12 or 13 which is a cytotoxic, cytostatic, or neutralizing
25 antibody.

15. A vaccine composition comprising the HP30 or HP56 polypeptide of claim 1 or comprising the HP30 polypeptide and HP56 polypeptide of claim 1 and a pharmaceutically acceptable carrier or diluent.

30

16. The vaccine of claim 15 further comprising one or more adjuvants or immunostimulatory compounds.

17. The vaccine of claim 16 wherein the adjuvants or immunostimulatory compounds
35 are selected from the group consisting of alum, mLT, QS21, MF59, CpG DNA, PML, calcium phosphate and PLG.

18. The vaccine of claim 16 comprising one adjuvant or immunostimulatory compound.
19. The vaccine of claim 16 comprising two different adjuvants or immunostimulatory compounds.
- 5 20. A vaccine comprising the peptide fragment of claim 6 and a pharmaceutically acceptable carrier or diluent.
21. A vaccine of claim 20 further comprising one or more adjuvants or
10 immunostimulating compounds.
22. The vaccine of claim 21 wherein the one or more adjuvants or immunostimulatory compounds are selected from the group consisting of alum, mLT, QS21, MF59, CpG DNA, PML, calcium phosphate and PLG.
- 15 23. The vaccine of claim 21 comprising one adjuvant or immunostimulatory compound.
24. The vaccine of claim 21 comprising two different adjuvants or immunostimulatory compounds.
- 20 25. A vaccine comprising the isolated fusion polypeptide of claim 8 and a pharmaceutically acceptable carrier or diluent.
26. The vaccine of claim 25 further comprising one or more adjuvants or
25 immunostimulatory compounds.
27. The vaccine of claim 26 wherein the one or more adjuvants or immunostimulatory compounds are selected from the group consisting of alum, mLT, QS21, MF59, CpG DNA, PML, calcium phosphate and PLG.
- 30 28. The vaccine of claim 26 comprising one adjuvant or immunostimulatory compound.
29. The vaccine of claim 26 comprising two different adjuvants or immunostimulatory compounds.
- 35

30. A vaccine comprising the antibody of claim 11 and a pharmaceutically acceptable carrier or diluent.
31. The vaccine any one of claims 15, 20 or 25 additionally comprising one or more immunogens selected from the group consisting of lipids, lipoproteins, phospholipids, lipooligosaccharides, proteins, attenuated organisms and inactivated whole cells.
32. The vaccine of claim 15, 20 or 25 additionally comprising one or more immunogens selected from the group consisting of *H. pylori* cytotoxin, *H. pylori* hsp60, *H. pylori* CagA, *H. pylori* urease, *H. pylori* catalase, *H. pylori* nickel binding protein, *H. pylori* tagA, *H. pylori* enolase, entire attenuated or killed organisms or subunits therefrom of *Campylobacter* spp., *Shigella* spp., Enteropathogenic *E. coli* spp, *Vibrio cholera* or rotavirus.
33. An isolated nucleic acid molecule comprising a nucleotide sequence encoding an isolated HP30 or HP56 polypeptide or an at least 6 amino acid fragment thereof, of *Helicobacter* spp, wherein the HP30 has a molecular weight 30 kDa and HP56 has a molecular weight of 56 kDa as determined in SDS polyacrylamide gel electrophoresis or fragment thereof.
34. An isolated nucleic acid molecule having the sequence of SEQ ID NO: 1 or 3, an at least 18 nucleotide fragment thereof, or the complement thereof.
35. A pharmaceutical composition comprising the isolated nucleic acid molecule of claim 33.
36. A vaccine comprising the isolated nucleic acid molecule of claim 33.
37. A vaccine comprising an isolated nucleic acid encoding the HP30 or HP56 polypeptide of claim 1 or an at least 18 nucleotide fragment thereof, and further comprising one or more adjuvants or immunostimulatory compounds which may be the same or different.
38. The vaccine of claim 37 wherein the one or more adjuvants or immunostimulatory compounds are selected from the group consisting of alum, MLT, QS21, MF59, CpG DNA, PML, calcium phosphate and PLG.

39. The vaccine of claim 37 comprising one adjuvant or immunostimulatory compound.
40. The vaccine of claim 37 comprising two different adjuvants or immunostimulatory compounds.
- 5 41. A vaccine comprising one or more of an isolated HP30 or HP56 polypeptide of *Helicobacter* spp. wherein the HP30 has a molecular weight of 30 kDa and HP56 kDa has a molecular weight of 56 kDa as determined in SDS of polyacrylamide gel electrophoresis; or an isolated nucleic acid comprising a nucleotide sequence encoding an HP30 or HP56
- 10 polypeptide *Helicobacter* spp. wherein the HP30 has a molecular weight of 30 kDa and HP56 kDa has a molecular weight of 56 kDa as determined in SDS of polyacrylamide gel electrophoresis said vaccine further comprising one or more adjuvants or immunostimulatory compounds selected from the group consisting of alum, mLT, QS21, MF59, CpG, DNA, PML, calcium phosphate and PLG.
- 15 42. A method of producing an immune response in an animal comprising administering to the animal an immunogenic amount of the HP30 or HP56 polypeptide of claim 1.
43. A method of producing an immune response in an animal comprising administering
- 20 to the animal an immunogenic amount of the peptide fragment of claim 6.
44. A method of producing an immune response in an animal comprising administering to the animal an immunogenic amount of the isolated fusion polypeptide of claim 8.
- 25 45. A method of producing an immune response in an animal comprising administering to the animal an immunogenic amount of the nucleic acid molecule of claims 33 or 34.
46. A method of producing an immune response in an animal comprising administering to the animal an immunogenic amount of the vaccine of claim 41.
- 30 47. A method of producing an immune response in an animal comprising administering to the animal an immunogenic amount of one or more vaccines of claims 15, 20, 25, 30, 36, 37 or 41, wherein said vaccine are administered simultaneously or sequentially.
- 35 48. Plasmid M15(PRE4)PQE/HP30 obtainable from *E. coli*, as deposited with the ATCC and assigned accession number PTA-2670.

49. Plasmid M15(PRE4)PQE/HP56 obtainable from *E.coli*, as deposited with the ATCC and assigned accession number PTA-2669.
50. A recombinant expression vector adapted for transformation of a host comprising
5 the nucleic acid molecule of claim 33 or 34.
51. The recombinant expression vector of claim 50 further comprising an expression means operatively coupled to the nucleic acid molecule for expression by the host of HP30 or HP56 protein or an at least 6 amino acid fragment thereof.
- 10 52. The expression vector of claim 51, wherein the expression means includes a nucleic acid portion encoding a sequence for purification of the HP30 or HP56 protein.
53. The expression vector of claim 51 wherein the expression means further includes a
15 nucleic acid portion that directs secretion from the host of the HP30 or HP56 polypeptide.
54. A transformed host cell containing an expression vector of claim 50.
55. The transformed host cell containing the plasmid of claim 48 or 49.
- 20 56. A host cell containing the nucleic acid molecule of claim 33 or 34 operatively linked to a heterologous promoter.
57. An isolated recombinant HP30 or HP56 polypeptide of *Helicobacter* spp. produced
25 by a method comprising culturing the transformed host cell of claim 54 under conditions suitable for expression of said HP30 or HP56 polypeptide and recovering said HP30 or HP56 polypeptide.
58. An isolated recombinant HP30 or HP56 polypeptide produced by a method
30 comprising culturing the transformed host cell of claim 55 under conditions suitable for expression said HP30 or HP56 polypeptide and recovering said HP30 or HP56 polypeptide.
59. An isolated recombinant HP30 or HP56 polypeptide produced by a method
35 comprising culturing the transformed host cell of claim 56 under conditions suitable for expression of said HP30 or HP56 polypeptide and recovering said HP30 or HP56 polypeptide.

60. A method of preventing, treating or ameliorating a disorder or disease associated with infection of an animal with *Helicobacter* by administering an effective amount of the polypeptide of claim 1.
- 5 61. A method of preventing, treating or ameliorating a disorder or disease associated with infection of an animal with *Helicobacter* by administering an effective amount of the polypeptide fragment of claim 6.
62. A method of preventing, treating or ameliorating a disorder or disease associated
10 with infection of an animal with *Helicobacter* by administering an effective amount of the isolated fusion polypeptide of claim 8.
63. A method of preventing, treating or ameliorating a disorder or disease associated
15 with infection of an animal with *Helicobacter* by administering an effective amount of the vaccine of claim 30.
64. A method of preventing, treating or ameliorating a disorder or disease associated
20 with infection of an animal with *Helicobacter* by administering an effective amount of the vaccine of claim 31.
65. A method of preventing, treating or ameliorating a disorder or disease associated with infection of an animal with *Helicobacter* by administering an effective amount of the vaccine of claim 32.
- 25 66. A method of preventing, treating or ameliorating a disorder or disease associated with infection of an animal with *Helicobacter* by administering an effective amount of the vaccine of claim 37.
67. A method of preventing, treating or ameliorating a disorder or disease associated
30 with infection of an animal with *Helicobacter* by administering an effective amount of the vaccine of claim 41.
68. A method of preventing, treating or ameliorating a disorder or disease associated
35 with infection of an animal with *Helicobacter* by administering an effective amount of the vaccine of claim 15.

69. A method of preventing, treating or ameliorating a disorder or disease associated with infection of an animal with *Helicobacter* by administering to a subject in need of such prevention, treatment or amelioration, an effective amount of one or more vaccines of claims 15, 20, 25, 30, 31, 36 or 41, each optionally comprising one or more immunogens
5 selected from the group consisting of a lipid, lipoprotein, phospholipid, lipopoligosaccharide, protein, attenuated organism and inactivated whole cell, wherein said vaccines are administered simultaneously or sequentially.
70. The method of claim 69 which further comprises administering one or more
10 antibiotics which has *Helicobacter* bactericidal activity wherein said antibiotic is administered prior to, simultaneously, or sequentially to the administration of said one or more vaccines.
71. The method of claim 70 wherein in said one or more antibiotics is selected from the
15 group consisting of meprazole, clarithromycin, omeprazole, metronidazole, tetracycline, Lansoprazole and amoxicillin.
72. An antagonist which inhibits the activity or expression of the polypeptide of claim 1.
- 20 73. An antagonist which inhibits the expression of the nucleic acid of claim 33.
74. A method for identifying compounds which interact with the polypeptide of claim 1, said method comprising contacting a composition comprising said polypeptide with the compound to be screened under conditions to permit interaction between the compound and
25 the polypeptide and detecting the interaction of the compound with the polypeptide.
75. A method for identifying compounds which interact with an activity of the nucleic acid molecule of claim 33, said method comprising contacting a composition comprising the nucleic acid with the compound to be screened under conditions to permit interaction
30 between the compound and the nucleic acid and detecting the interaction of the compound with the nucleic acid.
76. 76. A method of preventing, treating or ameliorating a disorder or disease associated with infection of an animal with *Helicobacter* by administering to a subject in need of such
35 prevention, treatment or amelioration, an effective amount of one or more vaccines of claim 32, each optionally comprising one or more immunogens selected from the group consisting

of a lipid, lipoprotein, phospholipid, lipoligosaccharide, protein, attenuated organism and inactivated whole cell, wherein said vaccines are administered simultaneously or sequentially.

5 77. The method of claim 76 which further comprises administering one or more antibiotics which has *Helicobacter* bactericidal activity wherein said antibiotic is administered prior to, simultaneously, or sequentially to the administration of said vaccine.

78. The method of claim 77 wherein in said one or more antibiotics is selected from the
10 group consisting of meprazole, clarithromycin, omeprazole, metronidazole, tetracycline, Lansoprazole and amoxicillin.

15

20

25

30

35